

Asia-Pacific Blood and Marrow Transplantation Group Registry

Version Number: 1.0

October 2016

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1. Background

The survey and reporting on hematopoietic cell transplantation and related therapy is essential for the proper development of hematopoietic cell transplantation therapy in the Asia Pacific region. The purpose of the Activity Survey and Outcome Registry carried out by the Asia-Pacific Blood and Marrow Transplantation Group (APBMT) is to enable a full understanding of the number of transplants being carried out, as well as their outcomes, and to generate a variety of useful information for the analysis of individual factors, such as geographic distribution, transplant types, illnesses and pathology, etc. Information on the number of transplants conducted in the region, as well as a country by country count, is reported as reference information to the World Health Organization (WHO) via the Worldwide Network for Blood and Marrow Transplantation (WBMT). Information by transplantation type and information related to prognoses are used to understand the current situation in this very geographically and ethnically diverse region, and also forms part of the foundation information that will underpin future development. This survey will be able to provide information that is extremely useful to patients, physicians and other medical professionals. The Data Center is sited at Department of Promotion for Blood and Marrow Transplantation, Aichi Medical University School of Medicine in Japan. The survey was begun as the 1st Activity Survey conducted by APBMT in 2007, and has been conducted, and its report published, every year since then. Further, the Outcome Registry was started in 2010, compiling the transplantation information since 2009. With the formal launch of the APBMT Outcome Registry Committee in November, 2015, the rules regarding the collection and management of data have been strengthened, as well as the cooperation of different countries in this survey.

2. Purpose

- To collect baseline and outcome data relating to all bone marrow, peripheral blood, cord blood hematopoietic stem cell transplants and therapies related to hematopoietic stem cell transplantation performed throughout the Asia Pacific area.
- To provide data to clinicians and researchers for studies involving specific subsets of patients, or to determine the feasibility of such studies.
- To provide data to clinicians to inform patient care.
- To provide data to health administrators for resource planning and quality assurance purposes.
- To participate in international data collections by contributing summary and outcome data to enhance the global knowledge base for these types of transplants.

3. Subjects

The survey has as its target all medical institutions (hereafter, “transplantation facilities”) involved in

hematopoietic cell transplantation and related therapy in Asia-Pacific region. The report subjects will be all kinds of hematopoietic stem cell transplantation, including autologous transplantation and allogenic transplantation (transplantation between blood relations, transplantation between non-blood relations, and transplantation of umbilical cord blood) and the related therapies. The data to be surveyed are transplant related clinical data of the patients and donors, and data related to prognoses. There will be no collection of specimens.

4. Methods

1) The Activity Survey comprises survey items on the numbers of transplants conducted from two years previous, by donor and transplantation source. The Data Center sends the APBMT Activity Survey Form every year to the Scientific Committee members of each country and region, and they then notify the transplantation facilities in their country or region. The transplantation facility then enters one year's actual performance data from the previous year into the form and submits the form to the data center within the prescribed time limit. Further, it is recommended that the data are submitted on a country basis.

2) In the Outcome Registry, the transplantation facilities register information about all transplants that they have conducted into the Least Minimum Dataset (LMD) survey item, as stipulated by APBMT. There are three types of questionnaire, i) day100_LMD sheet, ii) Disease_LMD sheet and iii) follow_LMD sheet. These forms can be downloaded from the APBMT website. For the first report, forms i) and ii) should be registered, then updated as form iii) every year subsequent to that. The Outcome Registry data are either mailed out or sent by email, depending on the situation of each country or region and transplantation facility. If the center reports its data to other registries, APBMT and a registry could agree on the data transmission or data sharing .

5. Explanation, consent and anonymity

The survey is conducted in an anonymous format in which data can only be linked back to individual patient information within the facility itself. Each transplantation facility needs to make sure that the details of the project have been fully explained to the patient before registering. Information reported to the Data Center will not contain any information that could identify individual patients, such as patient names or medical chart numbers, etc. However, sex, dates of birth, dates of transplantation and transplantation facility numbers will be reported along with the clinical data. The additional data from recipients and donors may be collected when needed for a specific study. In this case, data should be collected from their medical records, not from direct contact with recipients or donors.

6. Data management

The APBMT Data Center manages all information, including anonymous patient clinical information

(with personal information removed) and names and other personal information of contact physicians at cooperating facilities. The information is managed according to the APBMT Data Center's security policy.

7. Ethical policy

- 1) International participants in APBMT must follow their own national regulations and provide assurance to APBMT that national regulations are being followed.
- 2) The central ethical review of this protocol was approved by the Aichi Medical University ethics committee on October 24.
- 3) Where the use is intended for the purpose of evaluate, the decision will undergo an ethical review in the facility to which the researcher belongs.

8. Publication of results

The summary results will be described in outline on the APBMT website, and will be contained in the Annual Report.

9. Use of data and international cooperation

Use of data is judged by the APBMT Outcome Registry Committee, which exists within APBMT in order to manage data, and judges each data request based on its aims and scope of use. Data regarding the number of operations performed are reported to WHO every year, via WBMT, in cooperation with the effort to compile transplantation number data on a worldwide basis.

10. Research organization

The APBMT Outcome Registry is overseen by the APBMT Outcome Registry Committee and Data Center.

Chair: Yoshiko Atsuta

Vice Chair: Anthony Dodds, Aloysius Ho

Data Center: Minako Iida, Yukari Nakao